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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	

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Jenell Lawson
Intellectual Property
Cura Gen Corporation
555 Long Wharf Drive
New Haven, CT 06551

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,228	SHIMKETS, RICHARD A.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18 and 41-47, drawn to polynucleotides , classified in Class 536, subclass 23.5.

II. Claims 19-23, drawn to methods for detecting a polymorphism, classified in Class 435, subclass 6.

III. Claims 24-28, drawn to methods for determining the relatedness of subjects, classified in Class 435, subclass 6.

IV. Claims 29-31, drawn to polypeptides, classified in Class 530, subclass 350.

V. Claims 32-34, drawn to antibodies, classified in Class 530, subclass 387.1.

VI. Claim 35, drawn to a method of detection using an antibody, classified in Class 435, subclass 7.2.

VII. Claims 36, 37, and 40, drawn to a method of treatment by administering an polynucleotide, classified, for example, in Class 514, subclass 44.

VIII. Claim 38, drawn to a method of treatment by administering an protein, classified in Class 514, subclass 12.

IX. Claim 39, drawn to a method of treatment with an antibody, classified in Class 424, subclass 130.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, I and III, and I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions I and IV are patentably distinct in structure and physicochemical properties. Inventions I is drawn to nucleic acids whereas inventions III is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the products are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention IV do not require the particular products of the nucleic acids of inventions I since the proteins can be isolated from natural sources or chemically synthesized.

Inventions I and V are patentably distinct in structure and physicochemical properties. Invention I is drawn to nucleic acids whereas invention V is drawn to antibodies. The nucleic acids and antibodies differ in their structure, function and effect. While the nucleic acids of invention I consist of nucleotides, the antibodies of invention VIII encompass 2 heavy chains and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 CDRs that function to bind an epitope. The nucleic acids and antibodies also have different functional properties and can be utilized in different methodologies, such that nucleic acids may be used in hybridization methods, whereas antibodies may be used in protein

binding methods. Synthesis of the antibodies does not require the particular products of the nucleic acids of inventions I since the antibodies can be isolated from natural sources or chemically synthesized.

Inventions I and VI, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the nucleic acids of inventions I are not required to practice the ligand detection method of inventions VI, VIII and IX.

Inventions II, III, VI, VII, VIII and IX are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the different methods require the use of different reagents, involve different process steps and/or have different objectives and thereby have different functions and effects. In particular, the method of invention II requires nucleic acid probes and a sample nucleic acid and requires performing a probe hybridization assay to detect the present of a nucleic acid or a polymorphism in a nucleic acid. The method of invention III also nucleic acid probes and nucleic acid samples from 2 subjects and requires comparing the sequences of nucleic acids from 2 subjects in order to determine the relatedness of the subjects. The method of invention VI requires the use of proteins and antibodies and involves performing ligand binding assays in order to accomplish the

objective of detecting a protein. The method of invention VII requires the use of a nucleic acid and involves administering a nucleic acid in order to accomplish the objective of treating a subject suffering from a pathology associated with the presence of a polymorphism. The method of invention VIII requires the use of a protein and involves administering the protein to a subject in order to accomplish the objective of treating a subject suffering from a pathology associated with the presence of a polymorphism. The method of invention IX requires the use of an antibody and involves administering the antibody to a subject in order to accomplish the objective of treating a subject suffering from a pathology associated with the presence of a polymorphism.

Inventions IV and II, IV and III, IV and VII and IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the specific proteins of inventions IV are not required to practice the method set forth in invention II, III, VII, or IX.

Inventions IV and V are patentably distinct in structure and physicochemical properties. Invention II is drawn to proteins whereas invention III is drawn to antibodies. The proteins and antibodies differ in their primary amino acid sequence and in the secondary and tertiary structures. While the protein of invention IV is a single chain molecule, the antibody of invention III encompasses 2 heavy chains and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 CDRs that function to bind an epitope. The proteins and antibodies also have different functional properties and can be utilized in different methodologies.

Synthesis of the antibodies of inventions V does not require the particular products of the proteins of inventions IV since the antibodies can be isolated from natural sources or chemically synthesized. Further, antibodies which bind to an epitope of the protein of group IV may be known even if the protein is novel.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for synthesizing antibodies or for therapeutic purposes.

Inventions IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the proteins of invention II can be used in a materially different process, such as for synthesizing antibodies or for diagnostic purposes.

Inventions V and II, III, VII, VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP

808.01). In the instant case, the antibodies of invention V are not required to practice the methods of inventions II, III, VII, or VIII.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the antibodies of invention V can be used in a materially different process, such as for isolating proteins or for therapeutic purposes.

Inventions V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the antibodies of invention V can be used in a materially different process, such as for isolating proteins or for detecting proteins.

Sequence Election Requirement Applicable to Inventions I-IX

3. The claims have been presented in improper Markush format, as distinct products and distinct methods are improperly joined by the claims. Groups I-IX read on patentably distinct inventions drawn to multiple nucleic acid sequences, protein sequences and antibody sequences and methods of using these sequences. The claims encompass nucleic acids comprising one of the polymorphic sites of SEQ ID NO:

1-96, proteins encoded by said nucleic acids and antibodies to said proteins. Each nucleic acid consists of a different nucleotide sequence, has a different melting temperature and a different specificity of hybridization. For example, a nucleic acid comprising SEQ ID NO: 1 is chemically, structurally and functionally distinct from a nucleic acid comprising SEQ ID NO: 96. A search for a nucleic acid comprising SEQ ID NO: 1 would not be co-extensive with a search for a nucleic acid comprising SEQ ID NO: 96. Further, a finding that a nucleic acid comprising SEQ ID NO: 1, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that a nucleic acid comprising SEQ ID NO: 96 is also novel and unobvious over the prior art. Similarly, a finding that a nucleic acid comprising SEQ ID NO: 1 is anticipated or obvious over the prior art would not necessarily extend to a finding that a nucleic acid comprising SEQ ID NO: 96 is also anticipated or obvious over the prior art.

Each of the combinations of nucleic acids is also distinct from the individual nucleic acids because the combination of nucleic acids have distinct structural and functional properties. Additionally, a reference which renders obvious a single nucleic acid will not necessarily also render obvious a different nucleic acid or combination of nucleic acid. Similarly, a search indicating that a particular combination of nucleic acids is novel or unobvious would not extend to a holding that a single nucleic acid or a different combination of nucleic acids is also unobvious.

Similarly, each protein and each antibody to the protein consist of a different amino acid sequence, has a different binding specificity and a different biological

activity. Accordingly, each of the proteins of SEQ ID NO: 1-96 and antibodies to the proteins of SEQ ID NO :1-96 are distinct from one another.

Accordingly, the nucleic acids, proteins, antibodies and combinations thereof are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, **applicant should elect either one nucleic acid selected from the group consisting of SEQ ID NO: 1-96, one protein encoded by SEQ ID NO: 1-96, or one antibody to a protein encoded by SEQ ID NO: 1-96 or a particular combination of nucleic acids, proteins or antibodies.** It is noted that the claims appear to encompass different polymorphic variants of SEQ ID NO: 1-96. However, the reference in the claims to Table 1, column 5 is not clear because column 5 does not necessarily recite a polymorphic sequence (e.g., col 5 for SEQ ID NO :1 recites "gap(1)." To the extent that the claims include the polymorphisms listed in Table 1, col. 6, **Applicant is also required to elect one specific polymorphic site or one particular combination of sites, corresponding to the elected sequence**.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-IX require different searches that are not co-extensive. For instance, a literature and sequence search for the nucleic acids of invention I is not co-extensive with a literature and sequence search for the proteins of

invention IV or the antibodies of invention V or a search for the methods of inventions II, III, and VI-IX. Additionally, a search for each of the methods of inventions II, III, and VI-IX is not co-extensive with one another. For instance, a keyword / literature search for methods of detecting a nucleic acid (invention II) would not be co-extensive with a keyword / literature search for methods for treating a patient by administering a nucleic acid (invention VII). Further, a finding that the method of invention II is anticipated or obvious over the prior art would not necessarily extend to a finding that the method of inventions III or VI-IX were also anticipated or obvious over the prior art. Similarly, a finding that the method of invention VII is novel and unobvious over the prior art would not necessarily extend to a finding that the methods of invention II, III, VI, VIII or IX are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
May 17, 2006

CARLA J. MYERS
PRIMARY EXAMINER